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STATE FOR EAP/RSP/TC AND EB/TPP/BTA, STATE PASS AIT/W AND USTR, USTR FOR WINELAND AND WINTERS, USDOC FOR 4431/ITA/MAC/AP/OPB/TAIWAN/MBMORGAN AND JDUTTON

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TAGS: ECON ETRD TW
SUBJECT: PHRMA AND TAIWAN AGREE ON COMPUTER VALIDATION

REF: A. TAIPEI 3807

¶B. TAIPEI 2078

¶1. Summary: AIT and the Pharmaceutical Research Manufacturers Association (PhRMA), accompanied by representatives of Japanese and European pharmaceutical associations, met with Taiwan's Bureau of Food and Drug Analysis (BFDA) to discuss pharmaceutical validation requirements. The positive tone set by the new director general of the BFDA and the presence of other international pharmaceutical associations resulted in fruitful discussions that essentially resolved questions of computer validation requirements and led to progress on finalizing the methodology for determining which manufacturing sites will be the first to be inspected. End summary.

¶2. On September 13, AIT accompanied members of PhRMA, the Japanese Pharmaceutical Manufacturers Association (JPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) to meetings with BFDA, and Bureau of Pharmaceutical Affairs (BOPA)(reported reftel a.) In sharp contrast to PhRMA's April meeting on pharmaceutical validation with BFDA (reftel b), discussions this time were calm and productive. Both sides were well prepared and the reasonableness of the new BFDA Director General Chen Shu-kong was a welcome relief. Discussions focused on implementation of computer validation requirements (information on a pharmaceutical manufacturers computerized systems, training, and software and hardware management protocols) for manufacturing sites and clarifications on BFDA's method of calculating the Risk Priority Number (RPN) used to determine BFDA's inspection schedule.

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Japan and EU Weigh In on Computer Validation
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¶3. In response to Dr. Chen's initial question about requirements for computer validation by health authorities in other countries, JPMA representative Kenta Goto explained that in order to guarentee product quality, Japan has had a mandatory computer validation requirement in place for many years. Although Japan's laws and regulations covering computer validation have been subject to revision, the actual requirement has effectively been in place continuously since ¶1993. Malcolm Holmes, from EFPIA, informed Chen that an EU Directive required that all EU members must have a law requiring computer validation regimes in place in their national codes by April 2004. After that date, if no law existed, the EU regulation requiring the same would take precedence. Newly acceding EU states must be in compliance upon accession. Holmes added that several EU regulations and directives have addressed the issue of computer validation requirements since 1991.

¶4. BFDA agreed to accept government issued Certificates of Pharmaceutical Product from the US, Japan and the EU as effectively complying with the Taiwan requirement for computer validation, but requested more information from both the EU and Japan about their current regulations. Moreover, BFDA requested that manufacturing sites provide computer manuals and standard operating procedures or reference numbers of manuals for BFDA to review.

¶5. Guy Wingate, also from EFPIA and an expert on computer validation, responded that BFDA's over-reliance on documents as a means to prove the existence of good computer system practices was impractical. Wingate noted that most factories would have thousands of computerized systems operating simultaneously and with constantly changing procedures, providing manuals or reference numbers to BFDA for each of them would not only be an onerous requirement, it would be of questionable value. Instead, he suggested that a paragraph describing the structural testing regime and computer system lifecycle be included in the overview of manufacturing practices submitted by each company to BFDA. After some discussion and internal debate, BFDA agreed to consider EFPIA's proposal.

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Who Will Get Inspected First?
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¶6. Finally, the discussion turned to the methodology used by BFDA to compute the RPN. International pharmaceutical manufacturers disagree with the need for BFDA to conduct regular inspections of international pharmaceutical manufacturers, believe BFDA is more interested in creating a cadre of experienced inspectors through unnecessary inspections and are concerned that the weighting of several of the criteria, including extra emphasis on previous records of recalled products, was unbalanced. BFDA agreed to distinguish between voluntary and mandatory recalls in the determination of the RPN and to give a higher score to those areas with weak regulatory oversight. BFDA also agreed to keep confidential the RPN of each manufacturing site.

¶7. Comment: The patience and reasonableness of the new Director General of BFDA, as well as the sound preparation by experts from JPMA and EFPIA, were crucial to the success of this series of meetings. PhRMA and the other international pharmaceutical associations are not pleased by the prospect of their manufacturing operations being inspected by BFDA. They view this as a time-consuming and expensive endeavor, with limited value in the majority of cases. However, they appear to be resigned to this new requirement and can take heart from the fact the BFDA does not have the capacity to inspect more than a handful of sites each year -- their goal of 50 inspections in 2005 is likely to be closer to 20. The outline of the agreement on computer validation requirements appears to be a win for the industry, but as always, the proof will be in the shape of the published requirements, a copy of which BFDA promised to provide soon. End Comment. PAAL